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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/322,732	05/28/1999	KEITH R. MAROTTI	PUJ-0041	8413

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EXAMINER
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ROBINSON, HOPE A

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 07/02/2002

24

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/322,732

Applicant(s)

Marotti et al.

Examiner

Hope Robinson

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Apr 22, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-8, 15-18, and 140-150 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 15-18, and 140-150 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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### **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 22, 2002 has been entered.

### ***Claim Disposition***

2. Claims 1-3 have been canceled. Claims 142-150 have been added. Claims 4-8, 15-18 and 141 have been amended. Claims 4-8, 15-18 and 140-150 are pending.

### ***Claim Rejections - 35 U.S.C. § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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3. Claims 1-8, 15-18 and 140-150 are rejected under 35 U.S.C. 112 first paragraph, because the specification is not enabled for the full scope of the claims, for example a method for identifying a compound (unspecified) that increases the activity of efp by contacting efp with a compound (unspecified). There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. These factors include, but are not limited to: quantity of experimentation necessary, amount of direction or guidance presented, presence or absence of working examples, nature of the invention, state of the prior art, relative skill of those in the art, predictability or unpredictability of the art and breadth of the claims, these factors are addressed below.

The claimed invention is directed to a method which encompasses any and all possible compounds and a method step that utilizes the unidentified compound in the process and a method that does not identify the specific efp activity that is increased. Note that the claimed method appears to be a binding assay although not disclosed as such. However, the specification provides only examples and no specific assays to accompany the claimed method. Furthermore, there is no indicia of how the claimed method is an improvement over the prior art. See for example on page 14 where the specification states that cell-free extract is an example of an assay that can be performed. In addition, the specification asserts that contacting can take place in buffers or media well known to those skilled in the art. Further, varying amounts of the test compound can be used as desired by the practitioner. Therefore, it appears that much of the

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parameters involved in the method can be adjusted arbitrarily which invites one skilled in the art to perform undue experimentation.

Additionally, the specification asserts that the claimed method will identify a compound that modulates the activity of prokaryotic efp, determine whether the compound modifies activity of efp, for example determining if the compound binds to efp by a number of art-recognized procedures (i.e. binding assays such as gel-shift mobility electrophoresis, Western blot, filter binding and scintillation proximity assay). Note that the claimed method is relying on art-recognized procedures, yet the specification asserts that this is a new method/procedure. Furthermore, the information provided in the specification is exemplary and not limiting, therefore, does not breathe life into the claims. In view of the foregoing, one skilled in the art would have to engage in undue experimentation to be able to practice the full scope of the claims since the specification does not provide sufficient detail.

In the absence of sufficient guidance/direction regarding the steps to determine whether the test compound modulates the activity of efp one skilled in the art would not be able to practice the claimed invention commensurate in scope with the claims. Further, the claimed methods do not have endpoints/results that correspond to the preamble of the claims, thus, it doesn't appear that objective of the method is obtained. In fact the claims read on a binding assay rather than a method to identify an compound that has the desired effect on efp. In addition, the claims broadly recite a method of identifying a compound that modulates the activity of efp, however, there is no specific assay and measurements to obtain this information nor information

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as to whether modulation is up or down (see for example claim 141). Note for example that the prior art teaches that genes encoding certain ribosomal proteins can be deleted from the chromosome without an apparent effect on cell viability. It is also stated that most initiation, elongation and termination factors are required for cellular growth, however, some of these proteins may be dispensable under certain growth conditions (Aoki et al., The Journal of Biological Chemistry, vol. 272, no. 51, 1997). In view of the prior art the specification needs to provide guidance as to how the compound is determined, what the compound is, how the efp activity will be modulated, what effect the modulation will have on the function of the efp and a specific assay and measurement steps to achieve all of the above.

Absent exemplification of a specific assay to assay a specific compound the specification is not enabled for a method that modulates the activity of efp. Further, since no guidance or direction is provided regarding the determination of the test compound it would require undue experimentation to be able to practice the claimed invention.

Thus, for all of the above reasons, the specification is not considered to be enabling without undue experimentation, because, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to enable one skilled in the art to be able to practice the invention commensurate in scope with these claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 4-8, 15-18 and 140-150 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is indefinite because the claim recites “a method for identifying a compound that increases the activity of prokaryotic elongation factor p” and it is unclear what activity is being increased. The claim is also indefinite because the claim recites the step of “contacting efp with a unspecified compound” and as the method is geared towards identifying a compound it is unclear what compound will be contacted in the first step. The claim is further indefinite as to as there is no end result that indicates a specific compound has been identified, the method merely determines if binding occurred. With regard to the “determining” step, no measurement steps are included in the method. The claim is confusing as to the recitation of “wherein said intrinsic fluorescence of efp is measured as a function of the tryptophan residues of efp” as this limitation is unclear. It is suggested that the claim be amended to read “wherein said intrinsic fluorescence of efp is measured by the changes in the fluorescence of the tryptophan residue (s)” (as disclosed on page 18 of the specification). Item (b) of claim 1 is indefinite because the claim recites “increase or decreased fluorescence” which are two opposing activities in the same claim, it is suggested that applicant delete one of these terms from the claim. See also the dependent claims and independent claims that recite the above language (for example claim 5-8, 15-18 and 140-150).

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Claim 6 is indefinite because the claim recites the phrase “determining whether said compound which increases the activity of efp increases the activity of other protein(s) essential for the functioning of efp” and it is unclear what other proteins and what activities of the proteins are affected by the unspecified compound.

Claim 7 is indefinite because the claim recites “L16 protein” and the acronym is not preceded by the spelled out meaning of “L16” (see also claims 140 and 141). Note also that the claim is missing a transitional phrase, the claim should be amended as follows, “increases the activity of a L16 protein” (see also claims 141, 145).

Claims 140 and 141 are indefinite because the claims recite a method that modulates the activity of L16 protein. However, the claim does not recite whether modulation will be upward or downward. The claim is also indefinite as to the recitation of the L16 protein being in “association” with efp. What is this association?

5. Applicant's arguments filed on April 22, 2002 in Paper No. 23 has been fully considered however, the rejections under 35 U.S.C. 112, first and second paragraph remains. Regarding the rejection under 35 U.S.C. 112, second paragraph the response states that the claims have been amended to recite increases or decreases, however, note that this language still appears in claims as indicated above. Applicant also contends the word modulate is defined on page 10 of the specification which means increase or decrease. Applicant further states that the “Examiner has utterly failed to provide any evidence or reasoning why one skilled in the art would not be able to



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determine the metes and bounds of “an increase or decrease”. The specification defines the term as having two opposing meanings. Further, the limitations of the specification cannot be read into the claims. The claim as written is ambiguous thus indefinite because it a claim can be read to have two different meanings it is indefinite. Applicant need to recite one term in the claim and the word modulate needs to be deleted to clarify the claim. It is noted that applicant has already amended claims to recite either increase or decrease separately in the claims. Applicant contends that one skilled in the art would know that “in association” means that the L16 protein is bound to or forms a complex with efp. The word association implies a relationship with something else but does not define what that relationship is, thus if applicant intend for the association recited to be binding then this term should be recited in the claim. As the arguments presented are not persuasive the rejections remain.

With regard to the rejection under 35 U.S.C. 112, first paragraph applicant states that the claims have been amended to advance prosecution. However, the rejection remains as it is still applicable. Applicant also state that “activity” has been defined to mean a variety of measurable indicia suggesting or revealing binding, either direct or indirect, including, for example, the affinity of a compound for directly binding efp or a ribosome. As defined by applicant it is difficult to ascertain which activity is increased which is the point raised in the rejection. Since activity refers to a variety of measurable indicia how does one skilled in the art determine what activity will be affected by the method. In addition, applicant’s response states that there is no reason for applicant to identify a specific assay to identify a specific compound. This argument is not

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persuasive as the claims are directed to a method of identifying a compound, thus if there's no specific compound or assay how then will this method work. Thus, the rejection remains.

*Conclusion*

6. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Hope A. Robinson whose telephone number is (703)308-6231. The Examiner can normally be reached on Monday - Friday from 9:00 A.M. to 5:30 P.M. (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor Christopher S.F. Low, can be reached at (703)308-2932.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703)308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-2742. Please affix the Examiner's name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).




KAREN COCHRANE CARLSON, PH.D  
PRIMARY EXAMINER

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Hope A. Robinson, MS 

Patent Examiner